

### **REMARKS**

Claims 49, 54-63, 66, 72, 75, 77 and 79-80 are now pending. Claim 49 has been amended and is now directed to a polypeptide of SEQ ID NO: 3, 5 or 7. Claim 50 has been amended to delete the reference to variants. Claim 54 has been amended to include polypeptide fragments consisting of 9, 10 or 15 contiguous amino acids, support for which is found in Tables VII-XLIV. The remainder of the claims have been amended to make minor changes and clarify the subject matter of the invention. Claims 51-53, 64-65, 67-71, 73-74, 76 and 78 have been deleted without prejudice or disclaimer. Support for new claims 79-80 is found in the present application on page 49, first full paragraph.

### **Specification**

The Examiner has objected to the specification and claims for failing to comply with the Sequence Rules and for containing duplicate matter. Applicants respectfully disagree. Applicants have provided the sequences of the invention in Figure 2 and Figure 3. Specifically, 254P1D6B variant 1 (i.e. SEQ ID NO: 3) is the base sequence disclosed. Further variants of SEQ ID NO: 3 are identified in Example 5 and Example 6 and are graphically depicted in Figures 10-12. Additionally, Figures 2B-2D explicitly discloses the variants of SEQ ID NO: 3.

MPEP §2422.03 entitled The Requirements for a Sequence Listing and Sequence Identifiers; Sequences Embedded in Application Text; Variants of a Presented Sequence states, "It is generally acceptable to present a single, general sequence in accordance with the sequence rules and to discuss and/or claim variants of that general sequence without presenting each variant as a separate sequence in the "Sequence Listing."

Additionally, MPEP §2423.01 entitled, Format and Symbols To Be Used in Sequence Listings, states "To properly enter notations for modified codes in the Sequence Listing, the Feature section of the Sequence Listing should be used. That is, a modified base or amino acid may be presented in a given sequence as the corresponding unmodified base or amino acid if the modified

base or amino acid is one of those listed in WIPO Standard ST.25 (1998), Appendix 2, Table 2 or 4 and the modification is also set forth in the Feature section of the Sequence Listing.”

The rationale for this notation is stated in MPEP §2422.03 which states, “all of the implied variations [of a sequence] do not need to be included in the "Sequence Listing." If such a situation were encompassed by the rules, it would introduce far too much complexity into the "Sequence Listing" and the Office’s database. The possible mathematical variations that could result from this type of language could reasonably require a "Sequence Listing" that would be thousands of pages in length.”

Accordingly, Applicants have presented SEQ ID NO: 3 in the Sequence Listing and have noted amino acid modifications at residues 142, 157, and 612. Figure 11 discloses specific amino acid modifications at the relevant positions; however the specification discloses that other conservative modifications can occur. Thus, Applicants assert that the specification and the Sequence Listing properly reflect the sequences disclosed in the specification and request that the Examiner withdrawal the present objection.

#### Claim Objections

The Office objected to claims 61 and 64. Claim 64 has been deleted thus mooted the objection as to this claim. Claim 61 has been amended to include the word “response” before the word “comprises” as kindly suggested by the Examiner. Thus, these claim objections may be removed.

Applicants traverse the rejection of claim 72 under 35 U.S.C. § 101. Applicants appreciate the Examiner’s indication that referring to “an isolated” host cell would be remedial in overcoming this rejection and such amendment has been made to claim 72.

35 U.S.C. § 112

Applicants traverse the rejection of claims 49-78 under 35 U.S.C. § 112, second paragraph. Claim 49 has been amended to delete the reference to inducing a specific antibody response, the nucleotide sequence, and variant. Claim 54 has been reworded to refer to a fragment of the polypeptide of claim 49. Claims 50-53, 64-65, 67-71, 73-74, 76 and 78 have been canceled, thus mooting the rejection as to this claim.

Regarding the rejection of claim 56, with a reference to the tables in the specification, tables to which these claims refer are disclosed on pages 135-196 of the present application. As it is more concise to refer to the tables than to duplicate 60+ pages worth of tables into the claim, applicants respectfully submit that such incorporation by reference is an exceptional circumstance which is permitted by MPEP § 2173.05(s).

Thus, applicants request withdrawal of the indefiniteness rejection.

Applicants traverse the rejection of claims 49-52, 54-65, 67-68, 70-72, and 74-78 under 35 U.S.C. § 112, first paragraph (written description). The Office objects to the reference to “variants.” Claims 50-52, 64-65, 67-68, 70-72, 74 and 76 have been deleted, thus mooting the rejection as to these claims. The pending rejected claims have been amended to delete such reference and thus applicants respectfully submit that the present claims comply with the written description requirement. Thus, applicants respectfully request withdrawal of this rejection.

Applicants traverse the rejection of claims 70-72 under 35 U.S.C. § 112, first paragraph (enablement). Applicants have deleted claims 70-71 thus mooting the rejection as to these claims. It appears that claim 72 was included inadvertently in this rejection, as it is directed to a host cell. Thus, applicants request withdrawal of this rejection.

Applicants traverse the rejection of a) claims 49, 54, 55, 57-61, 63, 67 and 72 under 35 U.S.C. § 102(b) as anticipated by Cheever (U.S. patent No. 5,869,445); b) claims 74-77 under 35 U.S.C. § 102(b) as being anticipated by Cheever; c) claims 49 and 51-56 under 35 U.S.C. § 102(e) as anticipated by Ghosh (WO 03/087768); d) claims 49, 54 and 55 under

35 U.S.C. § 102(b) as being anticipated by Drmanac (WO 01/75067); e) claims 63, 67 and 68 under 35 U.S.C. § 102(a) as anticipated by Venter (WO 02/68579); and f) claim 78 under 35 U.S.C. § 103(a) as obvious over Venter in view of Reed (WO 02/26780). Claims 51-53, 67-68, 74 and 76 have been deleted, thus mooted the rejections as to these claims.

Cheever appears to disclose a polypeptide which does not have sequence similarity to SEQ ID NO: 3, 5, 7 or 11. As the present claims are now defined to require similarity to SEQ ID NO: 3, 5 or 7, applicants respectfully submit that the rejections based on Cheever may be properly withdrawn.

The Office alleges that Ghosh discloses a polypeptide which is identical to SEQ ID NO: 11. Applicants respectfully submit that the claims no longer include SEQ ID NO: 11. The Office alleges that Ghosh discloses human heart mitochondrial proteins, however, on page 114 of Ghosh, SEQ ID NO: 1622 is indicated as having an unknown description. Nonetheless, applicants respectfully submit that the present claims distinguish over Ghosh.

The Office alleges that Drmanac discloses residues 1-19 of SEQ ID NO: 3, 5 and 11. The present claims are directed to the full-length sequence of SEQ ID NO: 3, 5 or 7, polypeptides with conservative amino acid substitutions, and fragments which consists of 9, 10 or 15 contiguous amino acids of SEQ ID NO: 3, 5, 7 or 11. Thus, the fragments disclosed in Drmanac do not anticipate the polypeptide disclosed in the present claims. Thus, the rejection with respect to Drmanac may be properly withdrawn.

The Office alleges that Venter discloses a polynucleotide which is a variant of the claim sequences. Applicants respectfully submit that Venter does not read on the present claims. It appears from the alignment attached to the Office action that the sequence disclosed in Venter is at best, about 80% similar to the claimed full-length sequence. As such, applicants respectfully request withdrawal of the anticipation and obviousness rejections over Venter.

Conclusion

The claims have been amended such that all of the rejections have been addressed.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 511582008100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 15, 2006

Respectfully submitted,

By 

Carolyn A. Favorito

Registration No.: 39,183

MORRISON & FOERSTER LLP

12531 High Bluff Drive

Suite 100

San Diego, California 92130-2040

(858) 720-5195